IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID KESTER, et al.,	)	
	)	No. 1-11-cv-08196-CM
Plaintiffs,	)	
v.	)	
NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC, BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,	)	
Defendants.	)	

RELATOR'S MEMORANDUM OF LAW IN OPPOSITION TO PHARMACY DEFENDANTS' MOTIONS TO DISMISS THE RELATOR'S THIRD AMENDED COMPLAINT

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Relator David M. Kester ("Kester" or "Relator") respectfully submits this memorandum of law in opposition to the motions to dismiss filed by defendants Accredo Health Group, Inc., CuraScript, Inc., and CVS Caremark Corp. (now known as "CVS Health Corp.") on September 29, 2014 (Dkt. Nos. 275, 277). For the reasons stated herein, the pharmacy defendants' motions to dismiss Kester's Third Amended Complaint ("Complaint") should be denied.

PRELIMINARY STATEMENT

This Court has now set the ground rules for this case. The Court ordered Relator to replead some of the claims he asserted, and Relator followed the Court's instructions in the Third Amended Complaint ("TAC"). While the primary defendant in this case, Novartis, answered that complaint two weeks ago, the pharmacy defendants have filed another round of motions to dismiss. Their motions largely seek reconsideration of the Court's prior rulings. For the reasons set forth below, these motions should be denied.

Defendants first argue that the Court should reconsider its holdings on the "public disclosure" issue, but there is no basis for these belated requests. CVS points to no new disclosure, but rather argues that the 2008 consent decree (the same decree it raised earlier, in which the company pledged not to engage in any further fraud) should be deemed to bar suit for its misconduct until 2013, and not until March 2010 as the Court concluded. There is no basis for giving CVS such extraordinary immunity for acts of fraud committed five years after its consent decree, especially given the fact that CVS certified to the government every year that it no longer was engaged in any fraudulent acts. CuraScript and Accredo, which previously made public disclosure arguments that the Court rejected, now offer new, "me too" arguments raising prior lawsuits that they claim are similar to the one cited by CVS. Yet neither of those newfound disclosures even mentions Accredo or CuraScript; they refer only to the companies' corporate

parents. More importantly, these disclosures relate to misconduct by these defendants' corporate parents that took place before defendants were subsidiaries of those separate entities, and consequently relate to fraud that is wholly different from what Kester alleges here.

Second, the pharmacy defendants argue that despite the inclusion in the TAC of hundreds of examples of claims for payment that defendants submitted to Government payors for Gleevec, Tasigna, and TOBI, defendants still don't have adequate notice of the claims against them. This additional data is precisely what the Court called for in *Novartis II*, 2014 WL 2619014, at *9-10 (S.D.N.Y. June 10, 2014), and the fact that Novartis answered Relator's latest complaint should put an end to this argument. To the extent that defendants argue that Relator could not use claims data provided voluntarily by the states (and in compliance with HIPAA), there is no support for this view, and if adopted it would only serve to allow defendants to game the system and escape liability despite having full notice of the claims against them.

Third, Accredo and CuraScript seek reconsideration of this Court's certification rulings. They argue that under the Second Circuit's decision in *Mikes v. Straus*, a certification cannot be contained in the terms of a contract, such as an enrollment agreement. There is no support for the defendants' argument in *Mikes* or in any other authority. In fact, in *Mikes*, the Court recognized that "a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms" among other sources. 274 F.3d 687, 697 (2d Cir. 2001) (emphasis in *Mikes*) (quoting S. Rep. No. 99–345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274).

For these reasons, and those set forth further, below, defendants' motions to dismiss should be denied.

ARGUMENTS & AUTHORITIES

I. The Pharmacy Defendants' Public Disclosure Arguments Are Meritless

A. CVS's Argument for Reconsideration Should Be Rejected

In *Novartis V*, the Court held that Relator's allegations concerning CVS's involvement in the Novartis kickback scheme were "substantially similar" to accusations levied against CVS in a series of lawsuits brought by 28 state attorneys general, which concluded in a consent decree in 2008. *United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 2014 WL 4370597, at *9-*10 (Sept. 30, 2014) (*Novartis V*). However, the Court observed that information about a conspiracy that allegedly existed in 2007—and a settlement reached in early 2008—could not constitute a "public disclosure" of fraud several years later. *Id*. at *14-*16. For this reason, the Court imposed a March 2010 expiration date on CVS's proposed public disclosure, a date that coincides with the amendment of the FCA to remove "state court filings" as sources of public disclosures. *Id*. at *16. In its motion, CVS takes issue with the Court's decision, arguing that the consent decree should lead to an expiration date of February 14, 2013 instead, which was after Relator filed its lawsuit. CVS's argument is meritless and should be rejected.

First, CVS's argument ignores the reasoning in the Court's decision, and turns the public disclosure argument on its head. In *Novartis V*, the Court observed that a qualifying public disclosure must have "exposed all the essential elements of the alleged fraud." *Id*. at *9 (emphasis in original). A consent decree, whereby CVS agreed not to engage in further illegal conduct, and pursuant to which CVS certified on an annual basis that it was not engaged in misconduct, is the opposite of a disclosure that further fraudulent conduct was ongoing. If anything, the consent decree negated any prior disclosure of fraudulent conduct. The Court itself recognized this fact when it observed that the record contained "no evidence" of any public disclosure of ongoing wrongdoing after February 2008, and that "[i]ndeed, the Michigan consent

decree and the news articles regarding the settlement essentially represented to the public that [CVS] would not be involved in such a scheme after February 2008." *Id*. at *13. The Court held that the settlement would render the prior allegations of wrongdoing stale after a period of time. *See id.* at *15 ("No public disclosure revealed [CVS's] intention not to comply with its obligations under the settlement. Furthermore, as time went on, and 2008 became 2010 and even 2012, the information disclosed in connection with the 2008 settlement of the state enforcement actions became stale; that is, as it ceased to be contemporaneous, it became less and less suggestive of active, ongoing fraud."). CVS provides no additional evidence of a publicly disclosed fraud, and there is no basis for its argument that allegations concerning a fraud that allegedly ended in 2007 should immunize it from liability for acts committed five years after the settlement was reached.

This precise issue has already been addressed by the Court, and CVS's attempt to have this Court reconsider its prior ruling is unwarranted. It certainly does not meet the strict standards applicable to such requests. *See Panwar v. Access Therapies, Inc.,* 1:12-CV-00619-TWP, 2014 WL 2882914, at *2 (S.D. Ind. June 25, 2014) (where defendants raise new arguments in subsequent motion to dismiss, which could have been raised in earlier motion to dismiss, "the Court will treat Defendants' motion as a motion to reconsider"); *Perez v. Progenics Pharmaceuticals, Inc.*, No. 10 Civ. 8278, 2014 WL 4412477, at *3 (S.D.N.Y. Sept. 8, 2014) (noting that "[t]he standard of granting a motion for reconsideration under Local Rule 6.3 is strict," that such a motion "is not an opportunity for a losing party to advance new arguments to supplant those that failed in the prior briefing of the issue").

Indeed, based on CVS's representations in its brief, an earlier expiration date than March 2010 would appear to be warranted. The Court's reasoning in *Novartis V* was based on an

assumption that nothing happened after the 2008 consent decree: As "time went on, and 2008 became 2010," there was "[n]o public disclosure." *Novartis V*, at *15. Now we hear CVS trumpet the fact that the company was, all this time, annually "provid[ing] to the Attorney General of each Participating State a certification, signed by a [CVS] senior officer, certifying [CVS's] compliance with th[e] Consent Decree," and that it apparently was furnishing each year "a report showing the manner in which [CVS] ha[d] complied with the consent decree." CVS Br. at 5. Given that CVS was not only bound by the consent decree, which it was violating, but further certified falsely that it was in compliance with the terms of that decree, the expiration date of the public disclosure should have been the date of CVS's first certification to the government. As this Court noted, a "public disclosure" is information that would "'set the government squarely on the trail' of a specific defendant's participation in the fraud." *Novartis V*, at *10 (quoting *In re Natural Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009)). That trail went cold, at the latest, on the date that a senior officer of CVS certified to the government that the consent decree had worked, and the fraud was at an end. To hold otherwise would reward CVS—by immunizing it from Relator's separate and additional allegations—for having defrauded the government by falsely certifying its compliance with a binding consent decree. To the extent the Court agrees, Relator respectfully requests that the Court permit Relator to amend his allegations against CVS to begin CVS's liability on the date of CVS's first certification of compliance with the consent decree.

CVS also ignores the Court's reasons for using the March 2010 date. In March 2010, the FCA was amended such that state court filings no longer qualified as a potential source of a public disclosure. There is no basis to stretch a stale public disclosure beyond this date, especially given that the disclosure was based on state-court filings and, for claims submitted

from March 2010 and onward, such filings would not have triggered the public disclosure bar. There is no basis for the Court to reconsider its public disclosure holding with respect to CVS, except to move its expiration date backward in time, to the date of the first public "certification" by a "CVS senior officer" that the company was in compliance with the consent decree.

B. Accredo and CuraScript Fail to Identify Any Public Disclosure

For the first time, Accredo and CuraScript argue that they too were targets of suits "virtually identical" to the one against CVS, and that these suits should count as public disclosures as to them as well. Here again, these arguments could have been raised in their prior motions to dismiss, which contained other public disclosure arguments. ECF 178. Defendants implicitly concede that what they seek, in this second motion, is reconsideration of *Novartis V*. Accredo & CuraScript Br. at 3 (counsel "regret not pointing to these disclosed allegations in its prior motion"). While defendants certainly cannot meet the high standard for a motion for reconsideration, *see Perez*, 2014 WL 4412477, at *3, their "me too" arguments should be rejected under any standard.

1. Accredo

Accredo points to an October 2006 settlement of various *qui tam* actions filed against Accredo's current parent, Medco. Decl. of Daniel Meron in Supp. of Mot. to Dismiss TAC, Ex. 6, at 2. The argument fails for two reasons.

First, the settlement, by its express terms, does not apply to Accredo at all. The settlement covered Medco's misconduct between "January 1, 1995 and December 31, 2004." *Id.*, at 3, ¶ F. Medco did not acquire Accredo until August 2005, eight months later. Accredo, About Accredo (last visited Oct. 13, 2014), http://www.accredo.com/about-accredo(last visited Oct. 13, 2014). In short, the allegations of fraud at issue in this settlement did not pertain to Accredo at all. In *Novartis V*, the Court made clear that "[i]n order to bar claims against a

particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant ***as a participant in the alleged scheme***, or provide enough information about the participants in the scheme such that the defendant is identifiable." *Novartis V,* at *10 (emphasis added). The sources that Accredo cites prove that it was not a "participant in the alleged scheme."

Second, Accredo omits to mention that by the time of the settlement in October 2006, the facts were already at least two years out of date. All the pertinent facts were disclosed and admitted by April 2004 at the latest—a full two years prior to the ultimate settlement. In April 2004, Medco agreed to a consent decree going forward. U.S. Attorney's Office for the Eastern District of Pennsylvania, Press Release, U.S. Settles Its Anti-Fraud Claims for Injunctive Relief, 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions (Apr. 26, 2004) (Declaration of Steven M. Shepard, Ex. 1). The April 2004 consent decree "prohibit[ed] Medco from soliciting drug switches," and Medco promised to "[a]dopt the American Pharmacists Association code of ethics and principles of practice." *Id.* As a result, by April 2004, the U.S. Attorney was able to declare: "[W]e believe that the changes in Medco's business practices resulting from this agreement will positively impact health care consumers across the nation." *Id.*

In *Novartis V*, the Court set an expiration date of roughly two years from the date of the CVS consent decree. *Novartis V*, at *16. Even if the Court were to conclude that disclosures of Medco's misconduct constitute disclosures of misconduct by a company it had not yet acquired at the time of the misconduct, applying an equivalent "shelf life" to these disclosures would result in an expiration date of April 26, 2006. This would not bar Relator's claims against Accredo, as Relator alleges that the scheme in question began on or about January 1, 2007. *See*

Third Amend. Compl. ¶76 ("Beginning in or about January 2007 and continuing through the current time, Novartis management has employed a scheme to increase sales of certain specialty medications").

In sum, unlike the disclosures raised by CVS that were at issue in *Novartis V*, Medco's October 2006 settlement lacks any information about misconduct by the current defendant (Accredo) and pre-dates that defendant's alleged misconduct in this case by over three years.

2. CuraScript

CuraScript, like Accredo, trots out an old settlement between its corporate parent, Express Scripts, and several states, and claims that this settlement publicly disclosed Relator's current allegations against CuraScript. And like Accredo, CuraScript tries to align these allegations with those put forward by CVS and resolved in *Novartis V*. There are at least two critical and dispositive differences, any one of which would be reason to reject CuraScript's copycat effort out of hand.

First and foremost, CuraScript's proffered public disclosure concerns misconduct by its corporate parent Express Scripts, not CuraScript. Moreover, the disclosed misconduct upon which CuraScript relies—that Express Scripts persuaded patients and doctors to switch drugs in order to net larger rebates from drug makers—took place prior to Express Scripts' acquisition of CuraScript. For example, New York State, the first of many states to sue Express Scripts for the drug-switching misconduct, laid out the allegations against Express Scripts in great detail in its August 2004 complaint. That complaint named only Express Scripts and its subsidiary, ESI Mail Pharmacy Services, as defendants, and described wrongdoing that commenced in the 1990s. Complaint, *People v. Express Scripts*, No. 4699-04 (N.Y. Sup. Ct. Albany Aug. 4, 2004), http://www.ag.ny.gov/sites/default/files/pdfs/bureaus/health_care/ESI_Complaint%20(FINAL)%

20(08-03-04).pdf. Express Scripts didn't acquire CuraScript until the first quarter of 2004. CuraScript, In the Beginning (last visited Oct. 17, 2014), http://www.curascript.com/content/home_history.htm.

CuraScript's brief cites numerous articles about the multi-state investigations of Express Scripts that were launched in 2004 and culminated in the 2008 settlements attached to defendants' motion. Meron Decl. Ex 3, 4 & 5. If there had been a shred of evidence that CuraScript was involved in the misconduct, surely one of those articles would have mentioned it. But they didn't. Rather, the investigation concerned Express Scripts's misconduct in its Pharmacy Benefit Manager ("PBM") business, including actions taken by Express Scripts' own pharmacies. See Meron Decl., Ex. 2, at 3, ¶2(A) ("Respondent is a pharmacy benefit manager.")

CuraScript, though a subsidiary of Express Scripts, is a distinct corporate entity and a separate business. CuraScript operates primarily as a specialty pharmacy. *See* CuraScript, Who We Are (last visited Oct. 13, 2014), http://www.curascript.com/content/about_us.htm ("CuraScript specializes in providing specialty medications and support to individuals with chronic illnesses requiring these complex, high-cost therapies."). CuraScript committed the wrongdoing that is the subject of the instant lawsuit in the course of operating its specialty pharmacy business.

Fraud by one corporate entity within a conglomerate like Express Scripts is not "public disclosure" of fraud by others within the same conglomerate. Were the law otherwise, then a fraud by one entity within a conglomerate would immunize all the conglomerate's other entities from *qui tam* suits. That is not the law. *See Novartis V*, at *19 (because the "2008 public disclosures about Caremark's drug switching scheme did not mention Novartis, Accredo, or Curascript by name," and "gave no hint of these defendants' involvement such that they were

identifiable participants in the Caremark scheme," these "public disclosures do not bar the FCA claims against these [unnamed] defendants") (citing *United States ex rel. Baltazar v. Warden*, 635 F.3d 866, 868 (7th Cir. 2011)).

Second, the Express Scripts settlement lacks several key elements contained in Kester's complaint, including: (1) Novartis's involvement in the scheme, (2) the specific drugs at issue – Gleevec, Tasigna, TOBI and TOBI Podhaler, (3) access to Novartis's exclusive distribution network, including advantageous contract terms, provided as a *quid pro quo* for CuraScript's agreement to recommend Novartis's products, and (4) the pharmacies' efforts to increase dispensing of Novartis's product, including refills, through "high touch" nurse programs. *See United States ex rel. Kirk v. Schindler Elevator Corp.*, 437 F. App'x 13, 18 (2d Cir. 2011) (public-disclosure bar did not apply to the relator's "false reports" claims, which were "premised on alleged facts that were not publicly disclosed" in the disclosures that barred other claims by the relator; "critical elements of the false reports claims were not in the public domain").

Finally, even if the state investigation and settlement relating to Express Scripts counted as a public disclosure, that disclosure would, pursuant to the Court's analysis in *Novartis V*, bar only allegations of conduct occurring prior to March 2010. Even CuraScript appears to agree. *See* Accredo & Curascript Br. 6 (as to CuraScript, "§ 3730(e)(4) bars Relator's claims through at least March 2010").

C. Relator Satisfied the Original Source Requirement Under the FCA

Unless the Court elects to revisit its public disclosure holdings, it need not address the question of whether Relator may nonetheless continue against these defendants as an "original source." If the Court reaches that question, however, there is no basis for defendants' arguments against Relator's status as an original source.

The pre-2010 "public disclosure provision" defines "original source" as an individual "who has direct and independent knowledge of the information on which the allegations are based and has provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). The current version of the statute defines "original source" as someone "who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B)(ii) (as amended by PPACA in March 2010). Kester meets the requirements under both definitions.

First, with regard to the requirement that an original source have "direct and independent knowledge of the information" (pre-2010) or "independent" knowledge that "materially adds" to the public disclosure (post-2010) this Court held in *Novartis V* that Kester alleged such knowledge, as to Novartis, for the entire period; as to CVS, he had alleged it from March 2009 going forward. *Novartis V*, 2014 WL 4370597, at *18 (Relator has "direct and independent knowledge of Caremark's participation in the kickback scheme from March 2009 forward"). The only issue that remains for the Court to decide, under both the pre-2010 and post-2010 FCA, is whether Relator "provided the information to the Government before filing an action." *Id.* In *Novartis V*, the Court gave the parties "30 days to take discovery limited to the question of whether, when, and how Relator provided his information to the Government," to be followed by ten-page briefs on this issue. *Id.* at *19.

All three pharmacies cast aspersions on Relator because he elected to forgo one year of claims against CVS (from March 2009 to March 2010), rather than participate in a month's worth of defensive discovery on this issue. Relator did not make this decision because of some

perceived weakness or to hide any deficiency in his case. On the contrary: Rather than mire this case in a month of discovery on a collateral issue relevant to only one year's worth of damages against one defendant—for which Novartis would be jointly and severally liable anyway—Relator instead chose to spend the limited time and resources available for discovery to build a strong case of fraud against all of the defendants in the case.

Defendants also argue that Relator's disclosure of his draft complaint shortly before he filed suit disqualified him on grounds of timeliness. On November 11, 2011, three calendar days before the complaint was filed, Relator's counsel e-mailed a draft of the complaint to Heidi Wendell, who at the time was an Assistant U.S. Attorney in the U.S. Attorney's Office for the Southern District of New York, for her review prior to a November 14, 2011 meeting with counsel for Relator. (Declaration of Shelley R. Slade, Ex.1.)

With regard to defendants' argument that disclosure of a draft complaint shortly before filing doesn't meet the statutory "original source" requirement, neither the pre-2010 or post-2010 version of the original source provision includes any timing threshold for the voluntary provision of information to the government. Rather, the plain text of the statute only requires a relator to "provide the information before filing an action," which Relator plainly did. While CVS points to several authorities discussing various timing thresholds, CVS Br. at 9-10, these additional requirements have no basis in the statutory text.

The court in *United States v. Sanford-Brown, Ltd.*, No. 12-CIV-775, 2014 WL 1272098 (E.D. Wis. March 27, 2014) addressed this issue in depth. In that case, the relator sent a letter to the U.S. Attorney's office attaching his draft complaint three days before filing his action. As in this case, the defendants argued that the relator's disclosure was untimely, citing the same

authorities cited in CVS's brief. The court addressed these arguments in depth, but rejected any artificial time threshold, noting that the text of the statute "compel[led]" that reading. *Id*. at *7.

Accredo and Curascript further argue, in passing, that sending the complaint to the government is insufficiently detailed to satisfy the original source provision's pre-filing disclosure requirement, but they provide no authority for this proposition. On the contrary, other courts besides *Sanford-Brown* have ruled that pre-filing disclosure of a complaint satisfies the pre-filing disclosure requirement. *See Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1050 (8th Cir. 2002) (relator qualified as "original source" where its pre-filing disclosure consisted of a copy of a previously filed "anti-trust complaint"); *United States ex rel. Baker v. Cmty. Health Sys., Inc.*, 709 F. Supp. 2d 1084, 1104 (D.N.M. 2010) (relator qualified as "original source" where his pre-filing disclosure consisted of "a draft of the [complaint]"). Of course a complaint, by definition, sets forth the "information" on which the action is based.

Finally, CVS argues that the draft complaint may not have contained information specific to CVS. That is untrue. Relator has attached here, as Exhibit 1 to the Slade Declaration, the draft complaint supplied to the government. That draft includes the same allegations the Court relied on, in *Novartis V*, to find that Relator possessed "direct and independent knowledge of Caremark's participation in the scheme" from March 2009 to the present. *Compare Novartis V*, at *18 (citing Second Amend. Compl. ¶88), *with* Slade Decl., Ex. 1 ¶77 (identical allegation).

II. The TAC Alleges With Particularity Relator's (a)(1)(A) and (a)(1)(B) Claims Relating to Gleevec, Tasigna, and TOBI

In *Novartis I*, the Court held that for claims under subsections (a)(1)(A) or (a)(1)(B) of the FCA, a plaintiff must reasonably identify the false claims at issue. However, the Court did not hold that every false claim must be identified in the complaint. "Instead, the complaint must

provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue." *Novartis I*, 2014 WL 2324465, at *15 (S.D.N.Y. May 29, 2014). That is precisely what Relator did in the TAC.

The TAC states that CuraScript submitted to, and received payment from Medicare and Medicaid for, a substantial number of claims for Gleevec. The TAC cites as support a 2010 Specialty Drug Trend Report, compiled using CuraScript's own claims data for 650,000 Medicare and 2.15 million Medicaid beneficiaries, all of whom "used Curascript for specialty prescriptions." TAC, ¶156. The Trend Report states that Medicare Part D spending on Gleevec dispensed by CuraScript increased by 12.3% from 2009 to 2010, and that Gleevec was one of the "Top 10 Medicaid Specialty Drugs" in 2010 filled by CuraScript. *Id*. The complaint also notes that the pharmacy defendants inevitably submitted Medicare claims for Gleevec and Tasigna during the time period in question, as evidenced by the fact that these drugs are indicated for chronic myeloid leukemia, a disease which predominantly affects individuals 65 and over who would be Medicare recipients. *Id*., ¶157. The complaint further notes that federal and state governments maintain claims data regarding "the hundreds of thousands of claims filed on the federal-state Medicaid program, Medicare Part D and TRICARE by the Defendant pharmacies for Exjade, Myfortic, Gleevec, Tasigna, TOBI, and TOBI Podhaler during the time period at issue." *Id*., ¶156. Finally, taking heed of the Court's instruction that a plaintiff may satisfy the Rule 9(b) requirement by "providing example false claims," *Novartis I*, at *15, the TAC includes dozens of example Medicaid claims for Gleevec, Tasigna, and TOBI ***filled by CuraScript, Accredo, and CVS*** and ranging over ***nine*** different states. TAC, ¶158.

These allegations more than satisfy this Court's requirements for pleading an FCA violation under Rule 9(b), and consequently, Novartis answered that complaint two weeks ago.

The pharmacy defendants, however, have moved to dismiss the (a)(1)(A) and (a)(1)(B) claims against them relating to Gleevec, Tasigna, and TOBI for lack of particularity under Rule 9(b), despite having in their possession the data concerning the claims they submitted to the government. These arguments should be rejected.

First, CVS makes the factually inaccurate accusation that Relator obtained claims information from state governments in violation of HIPAA regulations. CVS Br. at 12. There is no basis for these accusations. Relator did not obtain any data from the states that disclose the identity of the patient. Relator obtained and set forth in the TAC the unique identifying numbers for claims, numbers apparent both in the records of the submitting pharmacy and the government health plan. CVS bases its accusation on the statement in the TAC that "[t]o protect patient privacy, Relator includes no individually-identifiable health information herein." TAC, ¶158. To the extent that CVS reads this to say that Relator possessed such information, that is simply wrong. It is also irrelevant to these proceedings. Unlike the *Cabotage* case cited by CVS where the plaintiff intended to use HIPAA protected information in the case, here, Relator is not attempting to use any individually-identifiable patient information in its complaint—indeed, the complaint expressly disclaims this. Thus, CVS's far-flung HIPAA allegations are factually inaccurate and irrelevant to the Rule 9(b) issue before the Court.

Second, to the extent that defendants argue that a complaint cannot include information obtained by the plaintiff through the voluntary cooperation of another, that is wrong. Indeed, CVS observes that if Relator obtained the examples in the complaint voluntarily, then the only potential issue would be whether HIPAA was violated, CVS Br. at 13, which it was not. Accredo and CuraScript point to one FCA case in which a motion was filed stating that "HHS objects to use of its subpoenaed documents to amend Relator's complaint." Accredo &

CuraScript Br. at 19. But that says nothing about whether information, when provided to the plaintiff with the consent of a state agency, can be utilized just as information obtained from a cooperating witness or other source can be in the normal course in civil litigation. The only other case Accredo and CuraScript can muster is totally inapposite and dealt with the court's ability to prevent a party from using proprietary materials improperly obtained, for instance confidential and privileged documents from another party. *SEC v. Brady*, 238 F.R.D. 429, 445 (N.D. Tex. 2006). That has nothing to do with Relator's use of information properly obtained and voluntarily provided by the state entities.

Third, defendants argue that the examples furnished in the complaint are not "representative" of the claims at issue, because they do not include Medicare or TRICARE claims, only Medicaid claims. Defendants have not explained why any further detail is necessary, especially given that the Court has acknowledged that the plaintiffs' theory does not focus on a subset of claims submitted to Medicare or Medicaid, but rather is that "every . . . claim . . . that a pharmacy submitted [to a government health care program] during the course of the kickback scheme was a 'false' claim because, even though the pharmacy had certified that it was not taking kickbacks in exchange for making recommendations, the pharmacy received a kickback for each sale-whether its recommendation yielded the prescription for that particular drug or not." *Novartis I,* at *21 (emphasis added). Defendants have identified no differences between the claims submitted among these programs that would require further detail to be pleaded to furnish adequate notice.

As the Court noted in *Novartis I*, "there is no published Second Circuit decision addressing the issue" of what exactly a relator must include, by way of claims data, in order to satisfy Rule 9(b)'s "particularity" requirement. *Novartis I*, at *9. After "survey[ing] the cases

from other Circuit courts," this Court cited, with approval, the Eleventh Circuit's rule on "particularity" in this context, as set forth in *United States ex rel. Clausen v. Lab. Corp. of America,* 290 F.3d 1301, 1308 (11th Cir. 2002). Under that standard—the standard this Court approved and adopted—the Eleventh Circuit has sustained complaints by relators that are similar to the TAC, *i.e.*, complaints in which the relator provides details for some, but by no means all, of a large number of claims. *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1226-27 (11th Cir. 2012) ("Although the Complaint's exhibits include details on only a portion of the accounts alleged to contain Overpayments, the inclusion of some records for some of the accounts is sufficient."); *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358-59 (11th Cir. 2006) (noting that while dates, amounts, and account numbers can provide particularity, Rule 9(b) does not mandate all of that information for each alleged claim, only "some of the information for at least some of the claims" (quoting *Clausen*, 290 F.3d at 1312 n. 21))).

When a plaintiff alleges that all claims of a readily-identifiable type—such as all claims for a particular off-label use or all claims for unauthorized services—the courts have ruled that the plaintiff has met the requirements of Rule 9(b) with regard to the element of a "false claim" so long as the plaintiff has alleged examples of such claims to one of the allegedly defrauded government health care programs; they do not require examples of claims to each and every government program that allegedly has been defrauded.

One such case is *United States ex rel. Booker v. Pfizer, Inc.*, 10-11166-DPW, 2014 WL 1271766, *16-*18 (D. Mass. Mar. 26, 2014). The relator alleged in that case that Pfizer caused pharmacies across the country to submit false claims to Medicare and Medicaid for the mental health drugs Geodon and Pristiq by marketing the drugs off-label and through kickbacks. The

sample claims described in the complaint related to only one of the drugs (Geodon) and were all submitted to Illinois Medicaid. Because the relator also alleged that certain of the doctors receiving kickbacks from Pfizer had a high percentage of Medicare and Medicaid patients, the court ruled that the relator had met Rule 9(b) as to the element of a "false claim." *Id.* at *16. District courts in New Jersey, Mississippi and Indiana have ruled similarly. *See United States ex rel. Judd v. Quest Diagnostics Inc.,* CIV. 10-4914 KM, 2014 WL 2435659, at *14-15 (D.N.J. May 30, 2014) (relator, who alleged damages to Medicare and Medicaid as a result of kickback-tainted claims, survived a 9(b) challenge by providing samples of Medicare but not Medicaid claims); *United States ex rel. Woods v. Southerncare, Inc.*, 3:09-CV-00313-CWR, 2013 WL 1339375 (S.D. Miss. Mar. 30, 2013) (relator, who alleged damages to "Medicare and/or Medicaid" for hospice care provided to ineligible patients, survived Rule 9(b) challenge by offering examples of services billed to Medicare but not Medicaid); *Abner v. Jewish Hosp. Health Care Servs.*, 4:05-CV-0106, 2008 WL 3853361 (S.D. Ind. Aug. 13, 2008) (relator, who alleged damages to Medicare and Medicaid when lab billed for tests not ordered by physicians, survived Rule 9(b) by providing samples of patient names and dates of treatment with no mention of government payers).

Defendants can find only one case in support of their view, *Mooney v. Americare, Inc.*, No. 06-CV-1806, 2013 WL 1346022, at *7 n.6 (E.D.N.Y. Apr. 3, 2013), in which the plaintiff pleaded 12 Medicare claims, but no Medicaid claims, and the Court in a footnote commented that the defendants did not have adequate notice of any false Medicaid claims. In *Mooney*, however, the alleged scheme did not involve all claims in a particular category. Rather it involved only those claims for which the defendants had altered the underlying medical records, and which were a fraction of the claims submitted for the services in question. *See* Third

Amend. Compl. ¶¶98, 100, *Mooney v. Americare, Inc.*, No. 06-CV-1806, 2012 WL 8498285 (E.D.N.Y. filed Jan. 24, 2012) (describing three different audits that found 46.8%, 23.3%, and 20.2% of records as having evidence of alteration). In that context, it would be impossible for the defendants to know based on what was pleaded which—if any—Medicaid claims were for patients whose medical records were allegedly altered. That is not this case here, where defendants know full well which claims are at issue (all Medicare and TRICARE claims during the time period in question). This is best reflected in the fact that Novartis answered the complaint, rather than making the specious Rule 9(b) argument that the pharmacy defendants now raise.

That defendants cite only one case, with readily distinguishable facts, is no accident. As Judge Gardephe recognized just last month in *United States ex rel. Billota v. Novartis Pharmaceuticals Corporation*, most of the courts that dismiss a False Claims Act complaint on Rule 9(b) grounds do so because the plaintiff has not identified even a single specific false claim. 11 CIV. 0071 PGG, 2014 WL 4922291 (S.D.N.Y. Sept. 30, 2014) ("The cases Novartis cites in support of its argument that the Government Entities have not sufficiently pled false claims are unpersuasive. In most of these cases, no particular false claims were alleged." (emphasis added)).

In any event, defendants overlook the specific allegations concerning Medicare, *see* TAC, ¶¶156-57, and the allegation that hundreds of thousands of claims were submitted by these pharmacies for Gleevec, Tasigna, and TOBI, made on information and belief, *id*. ¶158. *See Novartis II*, at *6 (noting that "the Second Circuit has stated that Rule 9(b) may be "relaxed" where key facts are "are peculiarly within the opposing party's knowledge," and the plaintiff has no access to those facts, in which case the plaintiff would be permitted to plead "on information and belief") (citing *Boykin v. Keycorp,* 521 F.3d 202, 215 (2d Cir. 2008)).

The pharmacy defendants' argument, if adopted, would satisfy none of the purposes of Rule 9(b). *See Novartis I*, 2014 WL 2324465, at *8 (identifying purposes of Rule 9(b) to "provide a defendant with fair notice of a plaintiff s claim, to safeguard a defendant's reputation from improvident charges of wrongdoing," "protect a defendant against the institution of a strike suit," and "discourage the filing of complaints as a pretext for discovery of unknown wrongs."). Defendants are well aware of their submission of claims to other states and governmental programs, submitted in the same time frame and manner as the claims to Medicaid identified in the TAC. Instead of genuinely seeking information needed to defend their conduct, the pharmacy defendants are seeking to game the system and use Rule 9(b) as a shield for alleged wrongs of which they have full notice. That is the opposite of what Rule 9(b) was designed to do, and the defendants' argument should be rejected. *See id.* ("A plaintiff must plead all the 'circumstances constituting fraud or mistake' with sufficient particularity to fulfill the purposes of Rule 9(b)." (emphasis added)).

As to the reverse false claims allegations, Relator has specifically alleged examples of "overpayments" to meet the particularity requirements of his "reverse false claims allegations" under Section 3720(a)(1)(G). With regard to Gleevec, Tasigna and TOBI, he has alleged reimbursement of the sample false claims involving Gleevec, Tasigna and TOBI set forth in Paragraph 158. See TAC ¶159 ("The government health care programs reimbursed the sample false claims listed above.") With regard to Exjade, he has alleged payment by Medicare or Medicaid of each of the sample false claims set forth in Paragraph 154. In alleging reimbursement of his sample false claims, he has alleged specific overpayments by the government payers. These are examples of the overpayments that Defendants illegally failed to disclose and refund to Medicare and Medicaid.

III. Accredo and CuraScript's Certification Arguments Are Meritless

Accredo and CuraScript challenge the existence of false certifications with respect to pre-2010 claims submitted to Medicare, certain state Medicaid programs, and TRICARE. Neither Novartis nor CVS have advanced this argument, and with good reason. In two separate decisions, *Novartis IV* and *Novartis V*, the Court held that Relator and the United States government had adequately pled the legal falsity of claims submitted to Medicare, TRICARE, and certain states' Medicaid programs, and gave leave to amend to allege express or implied certifications as to other state Medicaid programs, which Relator and United States government subsequently did. For a host of reasons, there is no need for the Court to re-examine its previous holdings.

A. Defendants' Argument That Contracts Cannot Be Certifications Should Be Rejected

In *Novartis IV* and *Novartis V*, the Court found that the pharmacies made express certifications of compliance with the AKS for Medicare Part D in the pharmacy subcontracts with Part D sponsors, which contained provisions "obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions." *Novartis IV*, at *12; *Novartis V*, at *28 ("For the reasons stated in *Novartis IV*, the Relator has adequately alleged that all the claims the pharmacies submitted to Medicare Part B and Medicare Part D during the course of the kickback scheme were rendered 'false' . . . ."). The Court observed that "[t]he AKS is unquestionably one of the 'applicable Federal laws' governing Medicare Part D that is cited in the subcontract certification." *Novartis IV*, at *12. The Court granted leave for Relator to amend his complaint to include similar express certifications for TRICARE and for state Medicaid programs other than New York, Illinois, Michigan and Florida. (As to New York, Illinois, Michigan, and Florida, this Court has already held that Relator has alleged legal falsity, *Novartis*

V, at *28, and defendants concede they have waived any objection to these express certifications, Accredo & CuraScript Br. at 14 n.6.) Relator followed the Court's instructions.

Accredo and CuraScript have responded with what is, in essence, a motion to reconsider this Court's ruling in *Novartis V*. *See* Accredo & CuraScript Br. at 12 (defendants' arguments would have been raised in a "renewal of a motion to dismiss" following this Court's decision in *Novartis V*, and were not raised at that time only because "before the time for filing a motion for reconsideration of *Novartis V* had expired, Relator filed his Third Amended Complaint"). Here again, defendants come nowhere close to meeting the high standard for such motions. *See Perez*, 2014 WL 4412477, at *3.

Accredo and CuraScript argue that a certification found in a contract cannot create FCA liability because a contract is a forward-looking promise rather than a representation of past or current behavior. That argument is flat wrong. There is nothing in *Mikes* or any other authority which precludes False Claims Act liability from flowing from a false promise to comply with a rule, like the AKS, that is a condition of payment. Indeed, *Mikes* acknowledged that claims submitted in knowing violation of contractual requirements can form the basis for liability, *Mikes*, 274 F.3d at 697. As the Second Circuit stated in *Mikes*, in amending the FCA in 1986, Congress made clear that "a false claim may take many forms, the most common being a claim for goods or services not provided, or ***provided in violation of contract terms***, specification, statute, or regulation." *Mikes,* 274 F. 3d at 697 (quoting S. Rep. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis in *Mikes*)).

As the Court has already ruled, contractual certifications can give rise to liability under the express, false certification theory. An express, false certification is a statement that "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is

a prerequisite to payment." *Mikes,* 274 F.3d at 698. Since the term "certification" is not used in the FCA itself, the term should not be applied rigidly or considered to have any "paramount and talismanic significance." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006). "So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, *or secret handshake*; False Claims liability can attach." *Id*. (emphasis added). Accordingly, a promise is just as much a certification as is a representation of current or prior conduct. The evidence will show that the pharmacies certified their compliance with the AKS on multiple enrollment forms and Part D subcontracts executed during the course of the scheme.[1] Defendants' argument that they could knowingly break the law despite repeatedly entering into contracts agreeing to operate lawfully, and bill the government without any repercussions under the FCA, would defy Congress's objectives.

Defendants cite only one case in support of the dubious proposition that a contractual promise cannot give rise to FCA liability: *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377-78 (4th Cir. 2008). That case did not even address the express certification theory of FCA liability, let alone rule that a breach of contract cannot give rise to a false or fraudulent claim under the FCA. Instead, the court held only that the particular contract in that case contained "general and relatively vague" requirements that did give rise to an "objective falsehood." *Id.*; *see also id.* at 379 ("[P]laintiffs have tried to shoehorn what might have been an ordinary FCA claim—and what really is a breach of contract suit—into some sort of fraudulent inducement action. This they simply cannot do.").

[1] Medicare Part D sponsor contracts are annual contracts. Medicaid programs require pharmacies to reenroll in a variety of situations, such as on an annual or triannual basis, when a pharmacy begins operating at a new location in the state, when a pharmacy's ownership changes (for instance, upon the 2011-2012 merger between MedCo and Express Scripts), or when the Medicaid state agency revises its enrollment agreement, something that happens often.

In a footnote, Accredo and CuraScript argue that Relator did not identify pre-March 2010 certifications in connection with North Dakota or New Hampshire. That is true as to North Dakota but not as to New Hampshire. Paragraph 64 of the TAC alleges an express certification in place since "at least March 2012." That is a sufficiently particularized allegation of express certification to entitle Relator to take discovery and prove that similar certifications were made throughout the period in question.

B. Defendants' Other Certification Arguments Are Meritless

Accredo and CuraScript also argue that there is no implied certification arising from statutes or regulations for any jurisdictions other than California and South Carolina. The Court need not reach this issue because, like Medicare Part D, each of these jurisdictions requires providers to certify compliance with the AKS in enrollment agreements that make clear that such certification is required before a pharmacy may bill and be paid by Medicaid. Nevertheless, Relator notes that, in addition to alleging false claims under the express certification theory of liability, he has also done so under an implied certification theory.

First, numerous courts have found liability under the implied certification theory based on broken contractual promises when the promise was material or a condition of payment. *See United States ex rel. Lemmon v. Envirocare of Utah, Inc*., 614 F.3d 1163, 1169 (10th Cir. 2010) (knowing violation of regulatory standards governing waste disposal set forth in contract); *United States v. SAIC*, 626 F.3d 1257 (D.C. Cir. 2010) (knowing violation of conflict of interest provision set forth in contract); *Shaw v. AAA Engineering & Drafting*, 213 F.3d 519 (10th Cir. 2000) (knowing violation of requirement in Air Force contract); *see also In re Bank of NY Mellon Corp*., 991 F. Supp. 2d 479, 496-97 (S.D.N.Y. 2014) (Kaplan, J.) ("Under [the implied certification] theory, a contractor's submission of a claim for payment is understood to be an implicit certification that it has complied with certain contractual or regulatory requirements.").

Second, a number of the jurisdictions in question do have laws conditioning Medicaid payment on compliance with anti-kickback law. Colorado, for example, provides that "NON-COMPLIANCE COULD RESULT IN NO PAYMENT FOR SERVICES RENDERED." Second Am. Compl. of the United States, ¶ 45. Accredo and CuraScript quibble with the use "could" and argue that because Colorado retains discretion to pay a claim even if the complaint fails to comply with its contractual requirements, there is no implied certification. But a state always has discretion to enforce a condition of payment or not; the question is whether providers are told that the failure to comply would forfeit their right to reimbursement, and that is unquestionably true here. Similarly, the Second Amended Complaint of the United States, and Relator's Third Amended Complaint, identify implied certifications for 36 other states, plus the District of Columbia.[2]

CONCLUSION

For the foregoing reasons, Relator respectfully submits that the motions to dismiss filed by the pharmacy defendants should be denied.

[2] Second Amend. Compl. of the United States, ¶42 (California); ¶49 (Connecticut); ¶51 (District of Columbia); ¶54 (Florida); ¶55 (Georgia); ¶59 (Illinois); ¶62 (Indiana); ¶68 (Kentucky); ¶71 (Maryland); ¶74 (Massachusetts); ¶77 (Michigan); ¶80 (Minnesota); ¶83 (Missouri); ¶88 (Nevada); ¶86 (New Jersey); ¶38 (New York); ¶94 (Ohio); ¶91 (Oklahoma); ¶97 (Oregon); ¶100 (Pennsylvania); ¶103 (South Carolina); ¶106 (Texas); ¶112 (Washington State); ¶115 (West Virginia); ¶118 (Wisconsin); TAC ¶56 (Hawaii); ¶57 (Idaho); ¶58 (Iowa); ¶59 (Louisiana); ¶60 (Maine); ¶63 (Nebraska); ¶65 (New Mexico); ¶67 (Rhode Island); ¶68 (South Dakota); ¶70 (Utah); ¶71 (Vermont); ¶72 (Wyoming).

Respectfully submitted,

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